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INT CL **A61B, A61M**
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(54) Title of the Invention: **Needle tip storage and removal device**
Abstract Title: **Needle Tip Storage and Removal Device**

(57) A needle tip storage and removal device is disclosed, comprising a housing with a separate storage compartment 16 and removal compartment 18 for receiving a needle tip. The removal compartment holds a used needle tip with a cylindrical skirt. The removal compartment 18 comprises a removal socket 28 and snap engagement means 30 for co-operating with the skirt of the needle. Preferably, the snap engagement means 30 comprises spaced arcuate rib portions directed radially inwardly around the periphery of the removal socket 28. The device may further comprise a closure element, movable between an open position in which the socket 28 is accessible, and a closed position where the socket 28 is closed. The closure element optionally further comprises a slidably mounted flexible member or a shutter. Optionally, the storage and removal compartments 16, 18 comprise a generally elongate socket and an elongate narrower passage. The storage and removal compartments 16, 18 may be oppositely directed

Fig. 2(a)

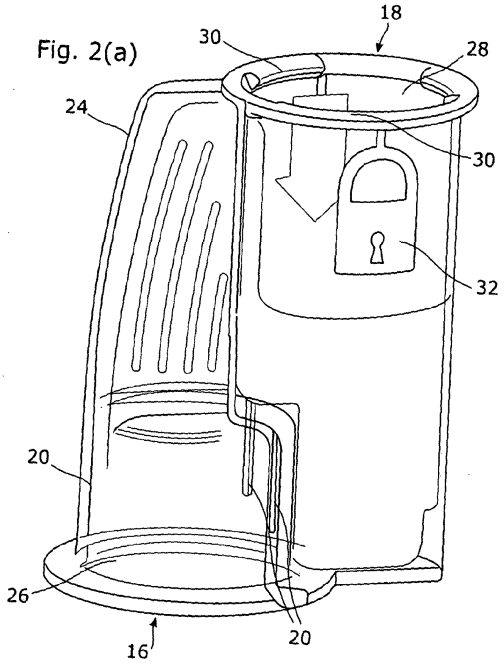
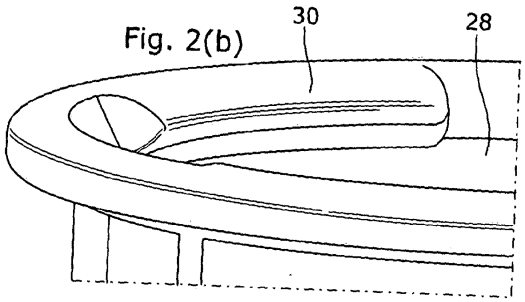


Fig. 2(b)



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At least one drawing originally filed was informal and the print reproduced here is taken from a later filed formal copy.

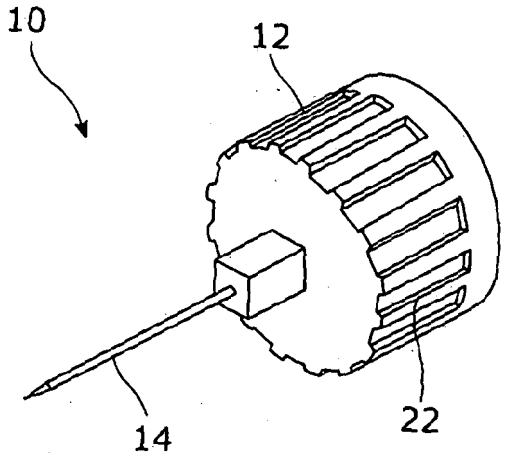


Fig. 1

Fig. 2(a)

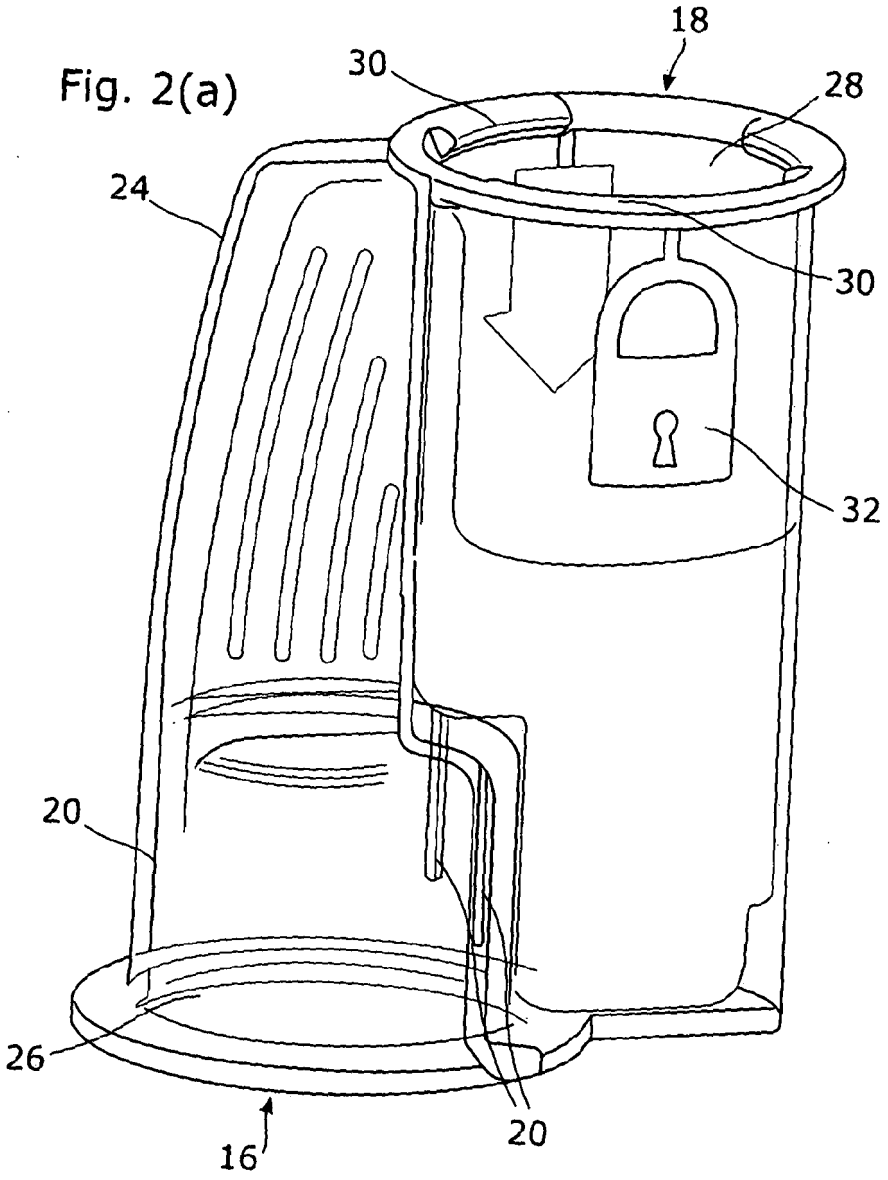
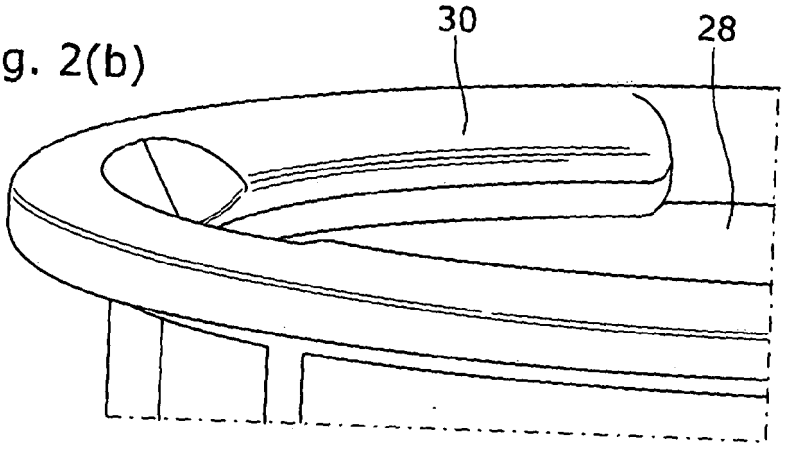


Fig. 2(b)



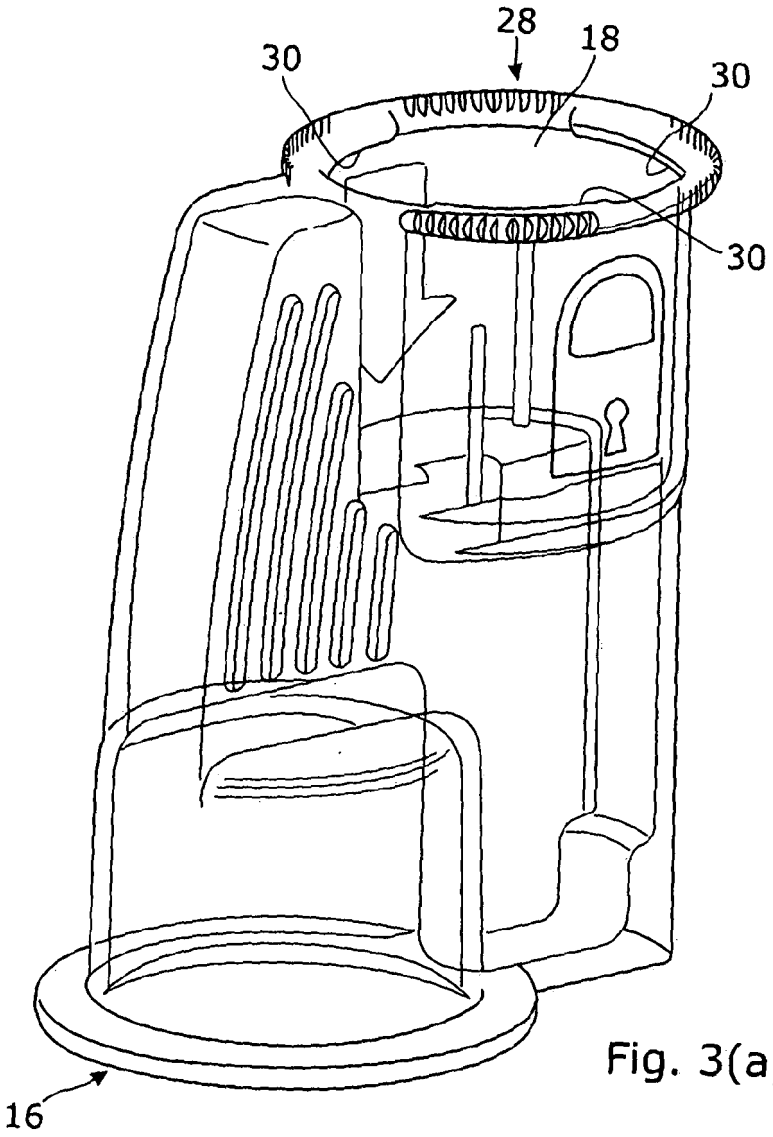


Fig. 3(a)

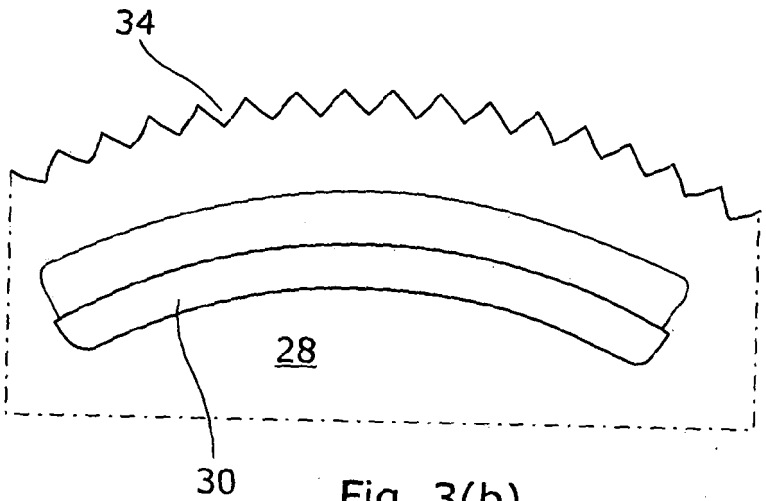
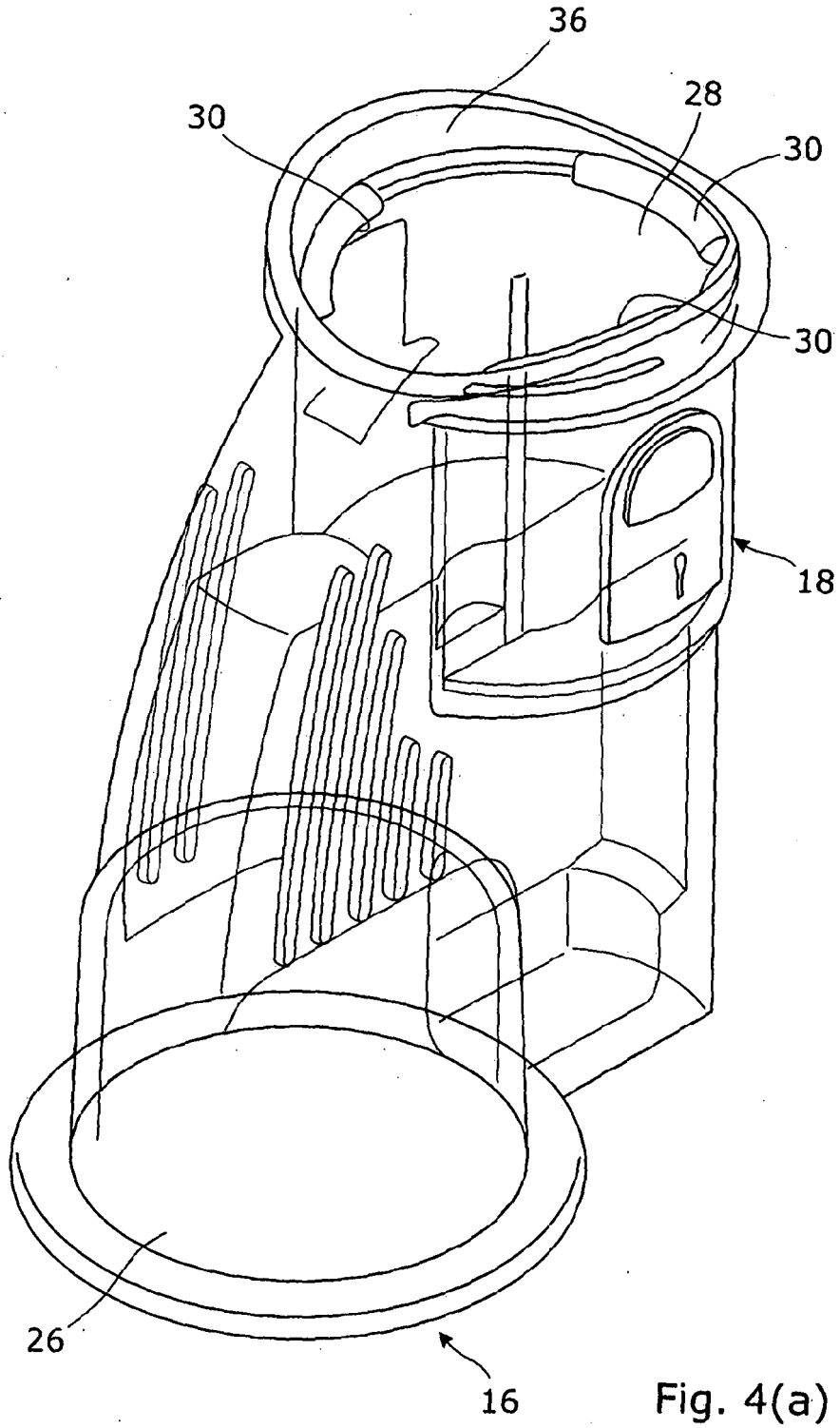


Fig. 3(b)



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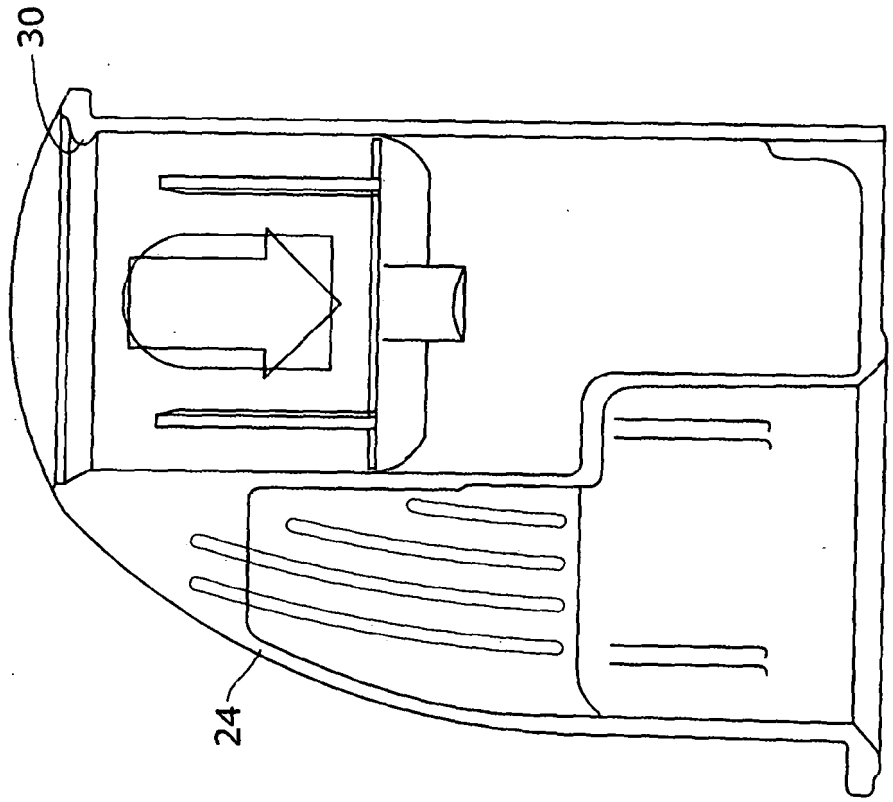


Fig. 4(c)

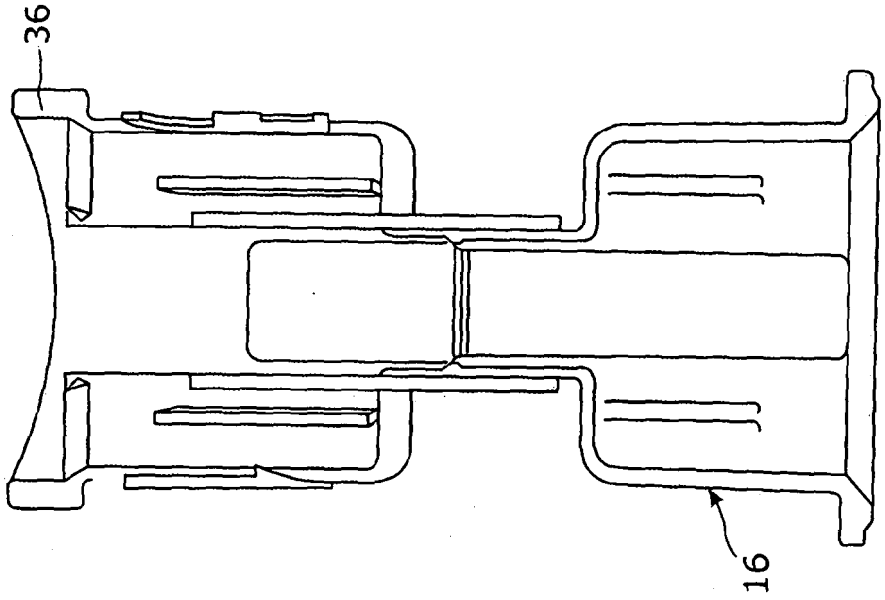


Fig. 4(b)

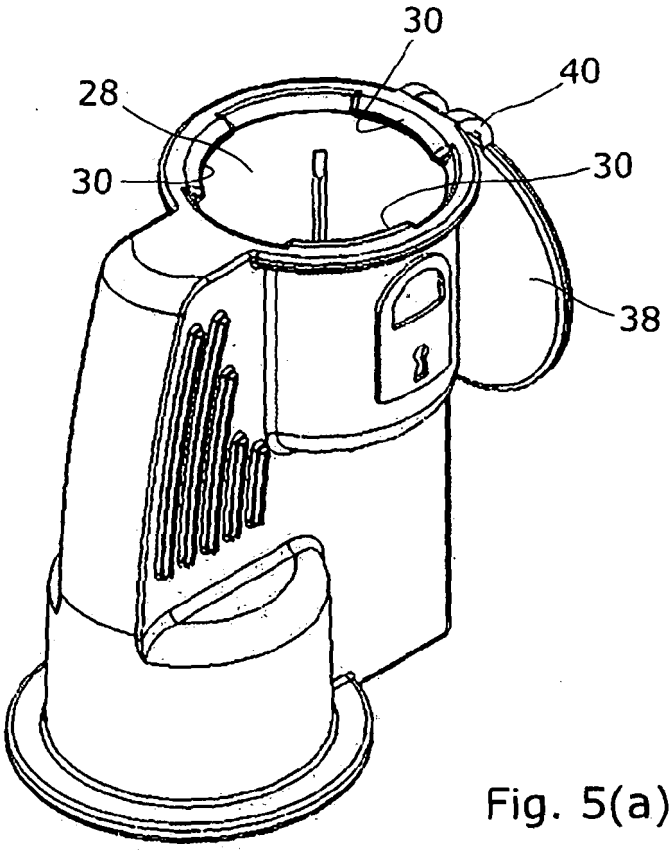


Fig. 5(a)

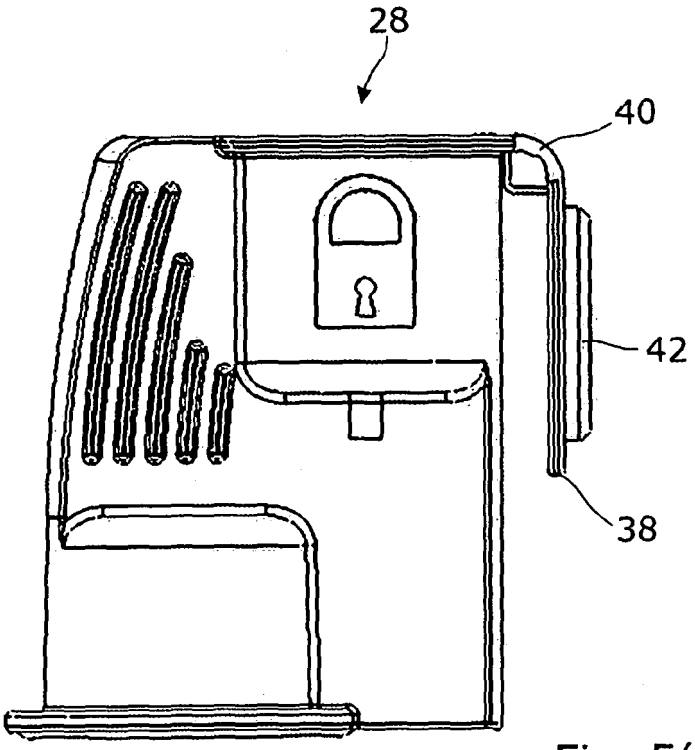


Fig. 5(b)

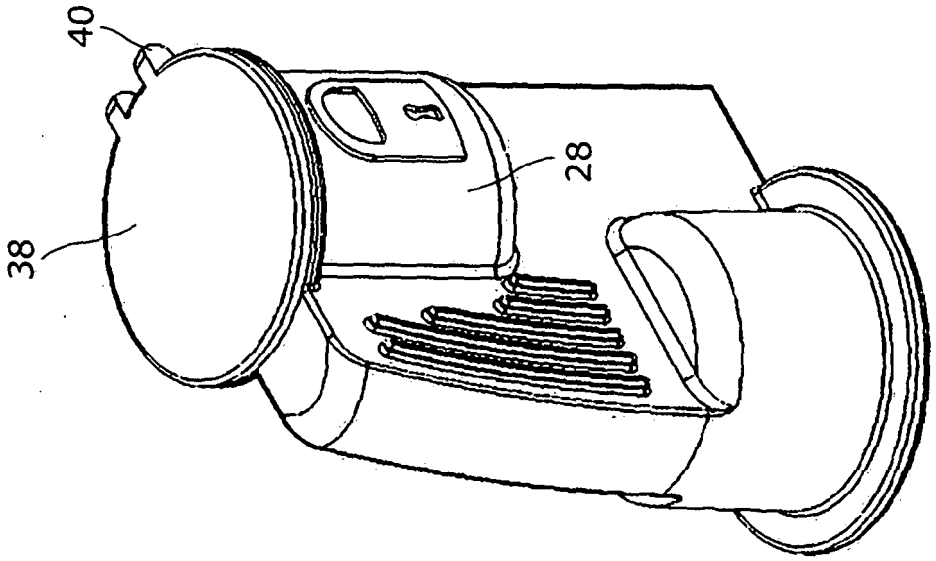


Fig. 5(d)

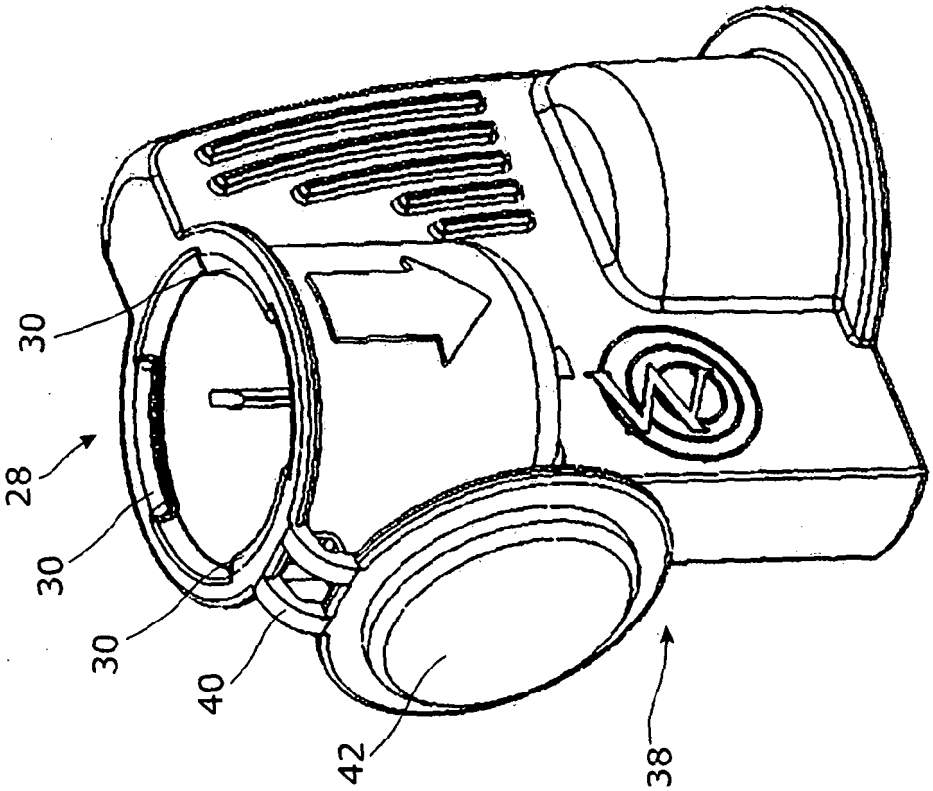


Fig. 5(c)

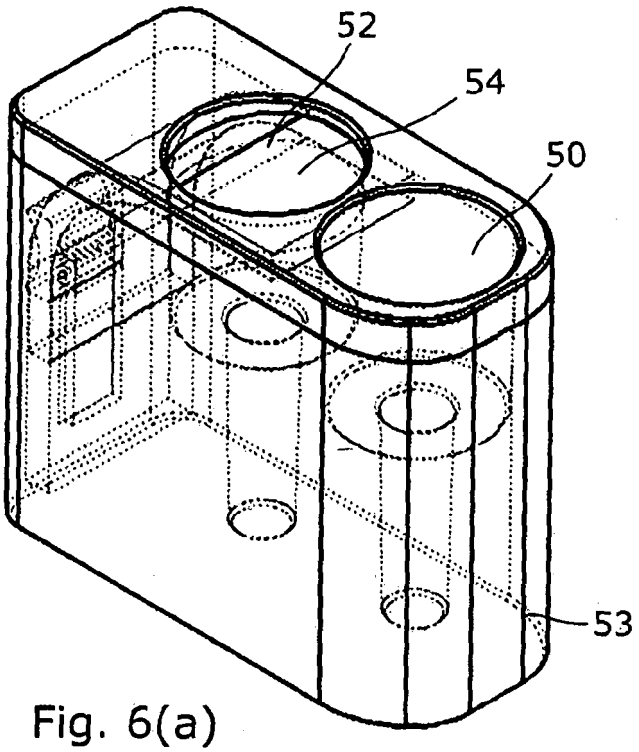


Fig. 6(a)

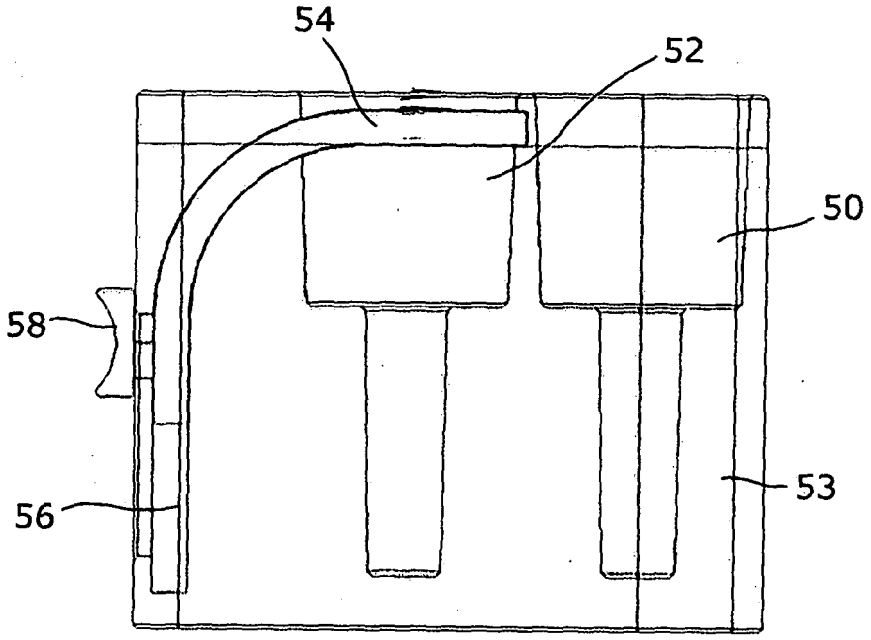


Fig. 6(b)

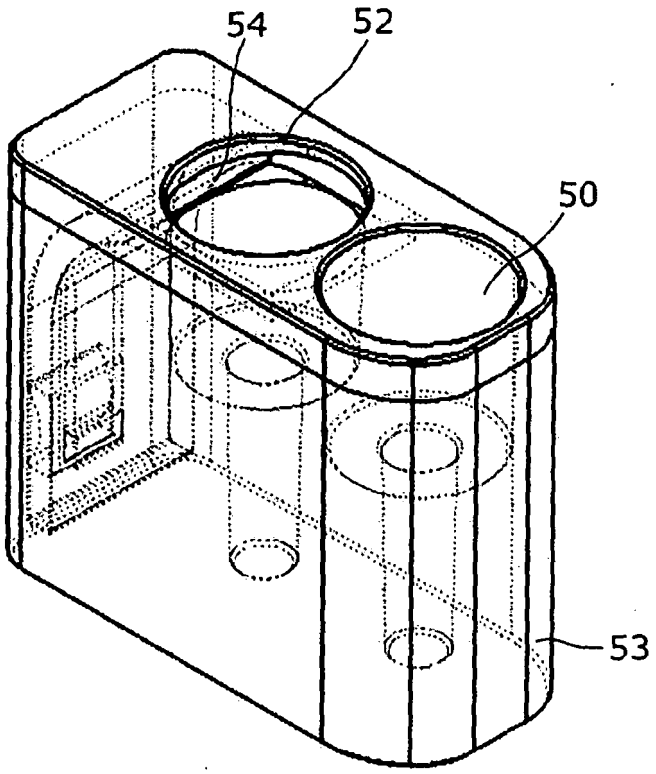


Fig. 6(c)

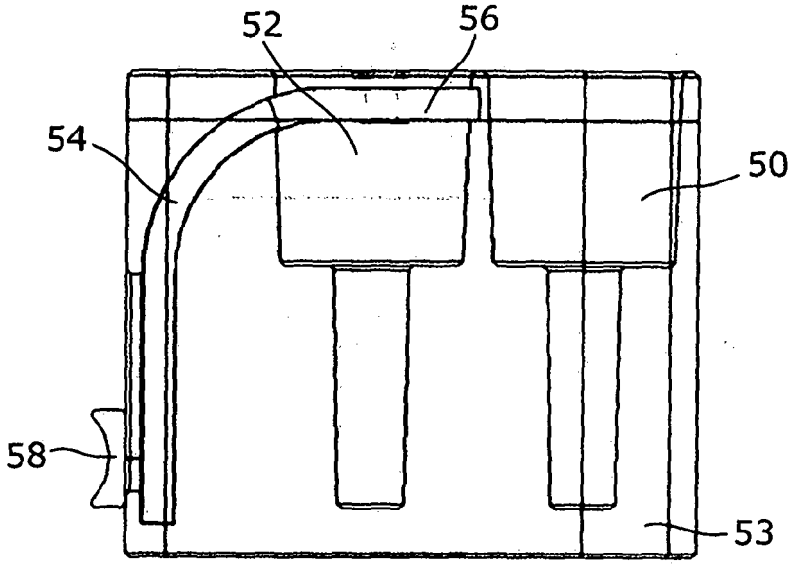


Fig. 6(d)

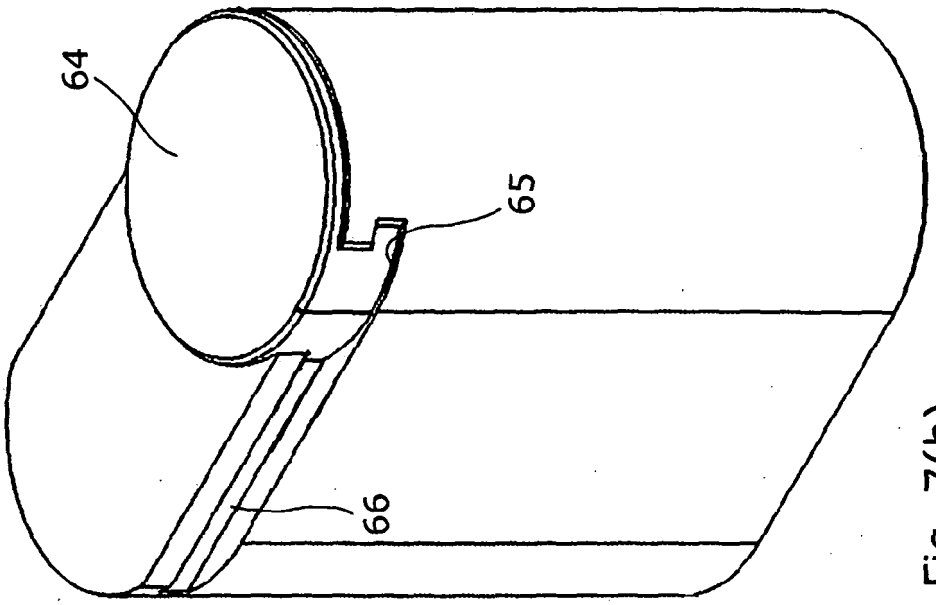


Fig. 7(b)

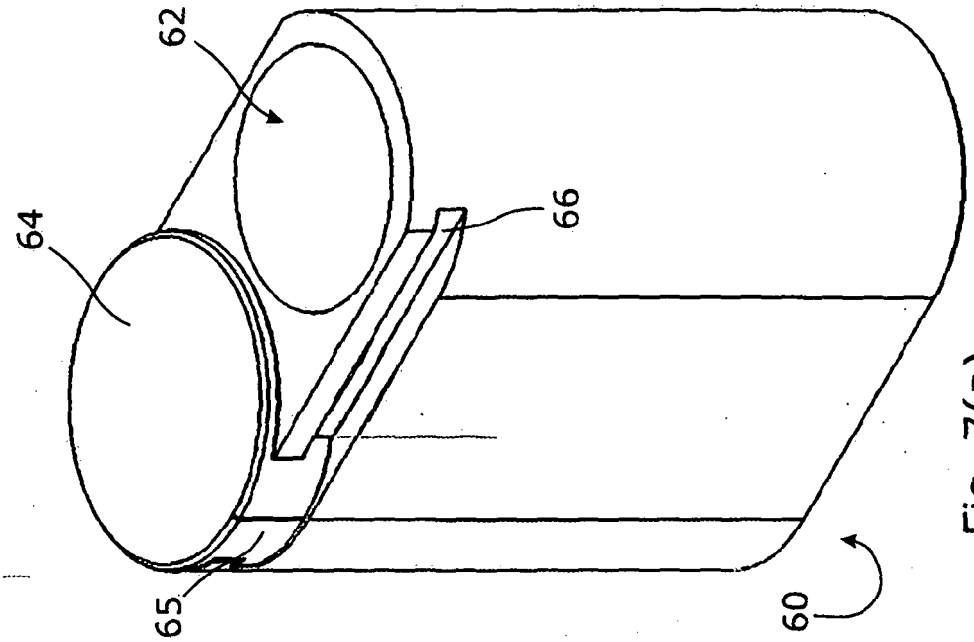


Fig. 7(a)

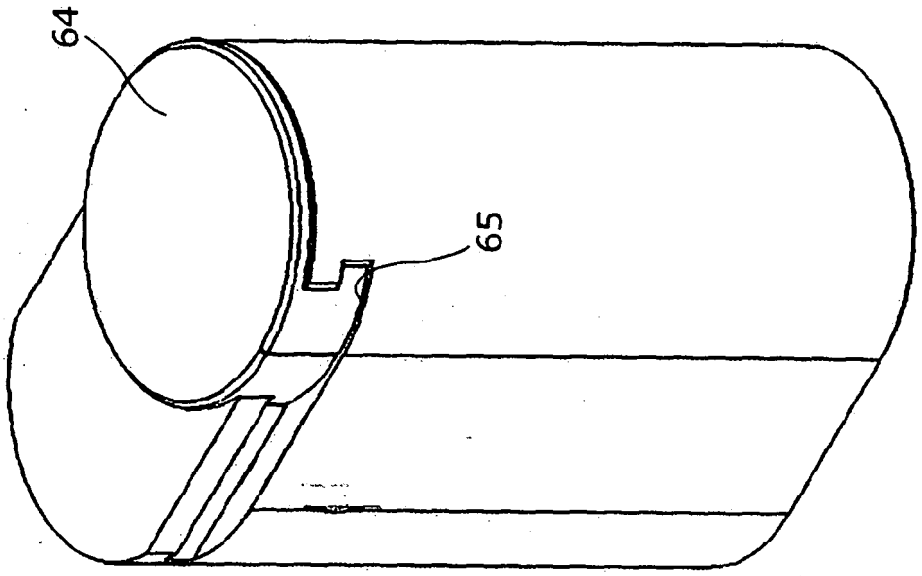
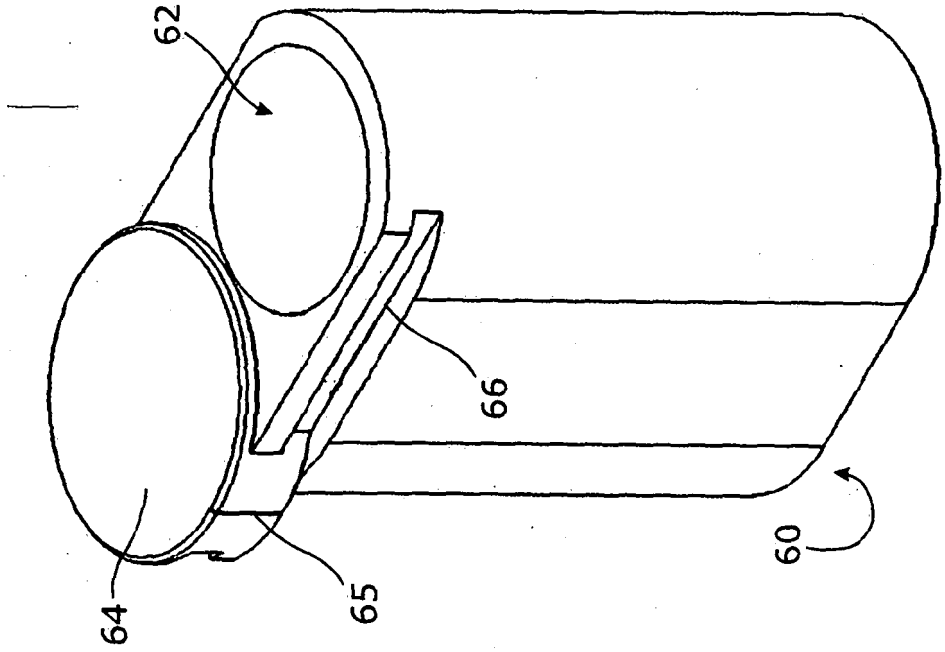


Fig. 8(b)



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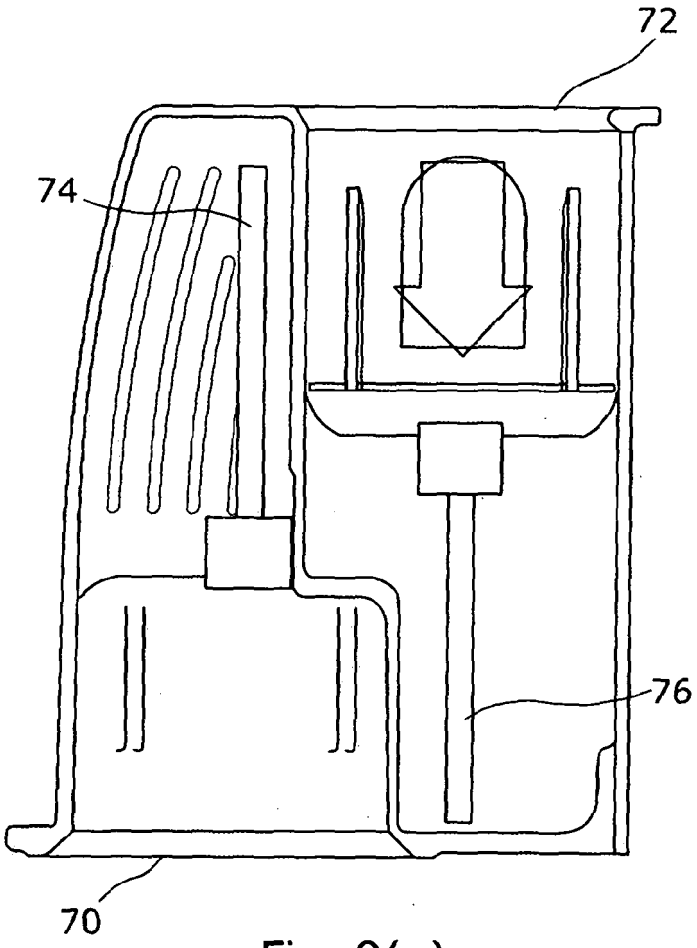

Fig. 9(a)

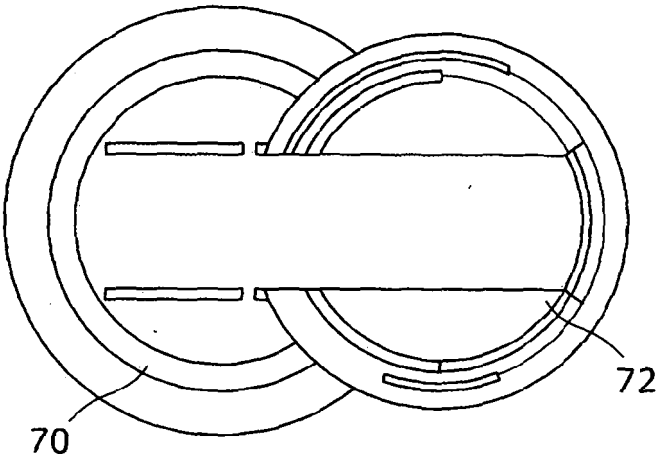

Fig. 9(b)

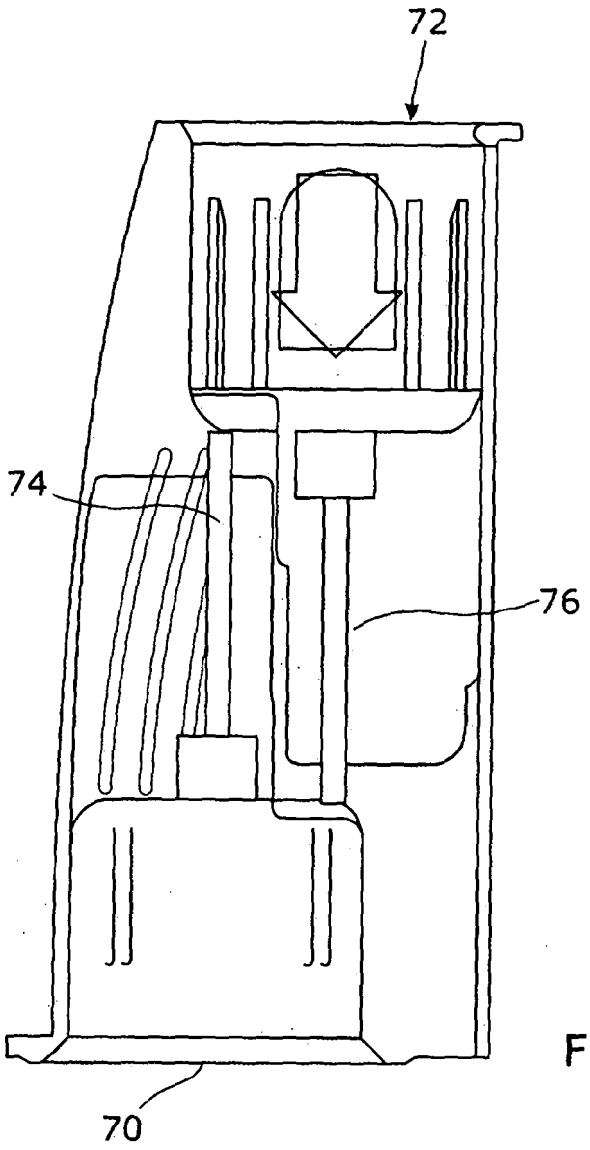

Fig. 10(a)

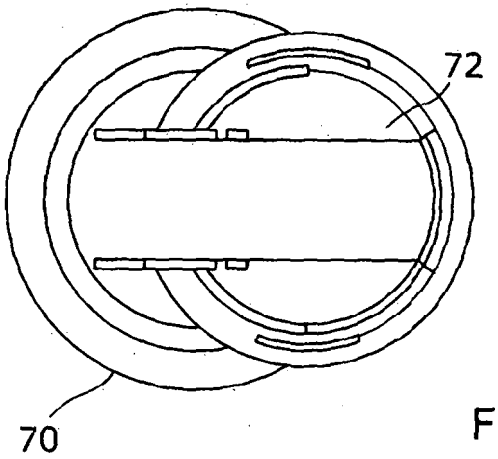

Fig. 10(b)

Needle Tip Storage and Removal Device

This invention relates to a needle tip storage and removal device and in particular, but not exclusively, to such a device for use with an injector apparatus intended to inject a number of metered doses from a cartridge of therapeutic material.

In a conventional automatic injector such as the Owen Mumford Autopen®, a cartridge of therapeutic material is loaded into a cartridge holder and a single use needle tip is screwed onto the forward end of the device. The needle tip has a double-ended needle, the rear end of which penetrates a rubber membrane in the forward end of the cartridge as the needle tip is screwed on. A metered dose can then be dialled into the automatic injector, the needle pushed into the injection site, and a trigger on the device actuated to inject the metered dose. After the injection, the needle tip should be removed from the device and discarded.

In many conventional arrangements, the exterior of the needle tip hub is provided with splines and the needle tip is supplied in a foil-sealed container, having a complementary splined socket in which the needle tip is supplied. To use such a needle tip, the foil is removed and the needle tip, with the needle still shrouded by the container is screwed onto the injection device using the container as a spanner. Once fully home, the container may be withdrawn axially leaving the needle exposed, although in some instances a removable secondary needle shield is provided. Following injection, the user may slide the container back onto the needle hub and use it as a spanner to remove the needle tip. The needle tip can then be safely discarded because the used needle is now

received in the container. This system works extremely well provided the user retains the container and uses it to remove the needle tip immediately after the injection. However, in many instances, users may not follow the recommendation to change the needle tip after each injection and may instead use the same needle tip for several injections over an extended period. In this case they may have discarded the original container and so may be left to remove the needle tip by unscrewing by hand it whilst the needle is still exposed. This provides a risk of needle stick injury both whilst removing the needle tip and when it is discarded.

Accordingly, in one aspect this invention provides a needle tip storage and removal device comprising a storage compartment for receiving in use an unused needle tip of a given drive configuration comprising a cylindrical skirt, and adjacent the storage compartment to a removal compartment for receiving in use a used needle tip of said given configuration, wherein the removal compartment includes a removal socket and snap engagement means adjacent the outer periphery of the socket for cooperating with said skirt to retain a used needle tip when pressed into said removal socket in use.

The snap engagement means may comprise spaced arcuate rib portions directed radially inwardly around the periphery of the removal socket. Thus the removal compartment may be formed of moulded plastics material, and the snap engagement means may be formed of a different plastics material, in an over-moulding process.

Conveniently, the removal socket is designed so that in use a used needle tip may be fully retained in said socket by said snap engagement means,

without protruding beyond the socket.

In one embodiment the storage container includes wall regions extending away from the socket to define a dished profile, when viewed in a direction transverse to a direction, in which a used needle tip is inserted into the removal compartment in use.

In another embodiment a peripheral flange extends around at least part of the periphery of the removal socket and has a textured surface, for example roughened, toothed or jagged.

The device may include a movable closure element associated with the device and movable between an open position in which the removal socket is accessible and a closed position in which the closure element closes the removal socket preventing access to the socket and any needle tip contained therein. The closure element may conveniently comprise a cap hinged to the device and hingeable between said open and closed positions. The cap and hinge may be integrally moulded with said removal compartment. The cap may include a feature that cooperates with a corresponding feature adjacent the socket to provide a snap engagement when the cap is closed.

In another embodiment, the closure element is slideable between said open and closed positions. Thus, said closure element may include a flexible member slideably mounted within an outer housing of said device and having an externally accessible pad for manual engagement to move said closure element between its open and closed positions.

Alternatively, said closure element may comprise a shutter mounted on the exterior of the device and movable between open and closed positions. The

shutter may include spaced claw members adapted to slide in corresponding tracks in an outer housing.

Preferably each of the storage and removal compartments comprises walls defining a generally cylindrical socket for the hub of the needle tip and, extending away therefrom, an elongate narrower passage to receive the needle of the needle tip, with the storage compartment and the removal compartment being oppositely directed.

In one arrangement the forward end of the passage in a given compartment lies alongside the cylindrical socket of the other, with the passages staggered longitudinally.

Alternatively, the passages may lie generally parallel and alongside each other and project towards the socket of the other compartment.

According to another aspect, this invention provides a needle tip storage and removal device comprising a storage compartment for receiving in use an unused needle tip of a given drive configuration comprising a cylindrical skirt, and adjacent the storage compartment to a removal compartment for receiving in use a used needle tip of said given configuration, wherein the removal compartment includes a movable closure element associated with the device which is movable between an open position in which the removal socket is accessible and a closed position in which the closure element closes the socket preventing access to the socket and any needle tip contained therein.

According to another aspect, this invention provides a needle tip storage and removal device comprising a storage compartment for receiving in use an unused needle tip of a given drive configuration comprising a cylindrical skirt,

and adjacent the storage compartment to a removal compartment for receiving in use a used needle tip of said given configuration, wherein each of the storage and removal compartments comprises walls defining a generally cylindrical socket for the hub of the needle tip, and extending away therefrom an elongate narrower passage to receive the needle of the needle tip, with the storage compartment and the removal compartment being oppositely directed, and wherein the forward end of the passage in a given compartment lies alongside the cylindrical socket of the other, in staggered configuration.

The storage and removal compartments preferably receive the needle tip non-rotationally so that the device can be used as a spanner to screw and unscrew the needle tip from the medicament container.

The invention also extends to a needle tip storage and removal device as described above with an unused needle tip located within the storage compartment and sealed therein by a removable closure of foil or the like.

By way of example only, various specific embodiments of the invention will be described in detail, reference being made to the accompanying drawings in which:

Figure 1 is a view of a typical needle tip with which the various embodiments below are intended to be used;

Figures 2(a) and (b) are side and detail views respectively on a first embodiment of needle tip storage and removal device in accordance with this invention;

Figures 3(a) and (b) are side and detail views on a second embodiment of needle tip storage and removal device in accordance with this invention;

Figures 4(a), (b) and (c) are perspective, side and front views respectively of a third embodiment of needle tip storage and removal device in accordance with this invention;

Figures 5(a) to (d) are views of a fourth embodiment of a needle tip storage and removal device in accordance with this invention;

Figures 6(a) to (d) are views of a fifth embodiment of a needle tip and storage and removal device in accordance with this invention in both the open and closed positions;

Figures 7(a) and 7(b) are side views of a sixth embodiment of a needle tip storage and removal device in accordance with this invention when in the open and closed positions respectively;

Figures 8(a) and (b) are side views of a seventh embodiment of a needle tip storage and removal device in accordance with this invention when in the open and closed positions respectively, and

Figures 9(a) and (b) and 10(a) and (b) are comparative views showing alternative configurations of a needle tip and storage removal device in accordance with this invention.

The needle tip storage and removal devices as to be described below are intended for use with a needle tip 10 of the type shown in Figure 1. The needle tip 10 comprises a generally cylindrical, splined needle hub 12 from the forward end of which extends a needle and which is threaded internally. The needle 14 is double ended and protrudes part way into the internally threaded cylindrical recess defined by the cylindrical skirt of the hub.

Referring generally to each of the described embodiments, these comprise a storage compartment 16 and a removal compartment 18. Each compartment is of similar form and comprises a socket portion designed to receive the needle hub and, communicating therewith, an elongate passage designed to accommodate the needle and any sheath provided therewith. Both the storage and removal compartments carry internal splines so that the needle tip may be slid into and out of the container but does not rotate in the compartment.

In a device as supplied, a sterile, unused needle tip 10 is housed in the storage compartment 16 and sealed by a foil seal (not shown), and the removal compartment 18 is empty. In use, assuming that the pen injector or the like has a used needle tip 10 on it, the needle tip storage and removal device is offered up to the needle tip so that the needle tip 10 slides into the removal compartment 18 in non-rotatable engagement, so that the pen injector can be unscrewed from the used needle tip. The used needle tip 10 is retained in the removal compartment 18 and the user then removes the foil seal or the like from the storage compartment 16 to reveal the sterile, unused needle tip. The user can then offer the pen injector up to the needle tip and screw it on. The embodiments below provide various safety features designed to improve the technical performance of the device; these features may be modified or combined.

Referring now to the embodiment of Figures 2(a) and (b), here the storage compartment 16 is shown with a cylindrical socket 26 which includes splines 20 adapted to cooperate with the splines 22 on the needle hub 12, and a

needle passage 24 extending away from the socket 26. This geometry is substantially reproduced in the removal compartment. At the outer periphery of the removal socket 28 there are provided a number of inwardly extending arcuate ribs 30 which define an aperture which is slightly smaller in diameter than the needle hub so that, when the needle hub 12 is pushed in, it snaps past the arcuate abutment ribs 30 to be retained thereby in the socket. When in this position, the needle hub 12 is held fully within the socket with no part thereof projecting beyond open end face of the socket. Conveniently, as shown in Figures 2(a) and (b), the arcuate abutment ribs 30 may be formed of a different plastics material to that from which the remainder of the device is moulded, having a contrasting collar and/or different material properties. For example, the device may be moulded in a two-shot moulding process with the abutments 30 and a suitable graphic symbol 32 such as that of a padlock and/or an arrow labelling the storage compartment for ease of use. The plastics material making up the abutments 30 may be designed to be more flexible than that of the remainder to facilitate the snap action.

Referring now to the embodiment of Figures 3(a) and (b), here the device is provided with a toothed flange 34 around the periphery of the socket 28 in the removal compartment 18 to differentiate it from the storage compartment 16.

Referring now to the embodiment of Figures 4(a) to (c), here an undulating wall portion 36 extends around the socket 28 in the storage compartment, again to allow the user to distinguish it from the removal compartment. The undulating wall ensures that there is only one stable vertical

orientation for the device, i.e. that as the device is viewed in Figure 4, with the storage compartment facing downwards.

Referring now to Figures 5(a) to (d), in this arrangement, the embodiment of Figure 1 is supplemented by the provision of a cap 38 which is hinged to a wall portion of the device adjacent the socket in the storage compartment by a live hinge 40. The cap has a plug 42 that cooperates with the abutments 30 so that the cap may be snapped 38 shut to prevent access to the used needle tip 10 once it has been inserted into the storage compartment and snapped past the abutments 30.

Referring now to the embodiment of Figures 6(a) to (d), in this arrangement the splined storage compartment 50 and the removal compartment 52 are arranged side by side in the same orientation in a housing 53 which slideably mounts a flexible cover element 54. The cover element runs in a curved, L-shaped track 56 within the housing, with a thumb pad 58 extending through a slot in the housing so that the flexible cover can be slid from the open position shown in Figures 6(c) and (d) and the closed position shown in Figures 6(a) and (b) by sliding the thumb pad 58. If required, the device could be supplied with the shutter in the open position with a non-return catch being provided between the shutter and the housing to prevent reopening of the storage container once the shutter has been closed.

Referring now to the embodiments of Figures 7 and 8, in these arrangements the storage and removal compartments 60, 62 are oppositely directed as in the embodiments of Figures 1 to 5. In the views as shown, a disk shaped cover 64 has clips 65 which clip in opposite tracks 66 in the exterior of

the housing (only one of which is shown) so that the cover can be slid between an open position (Figures 7(a), Figure 8(a)) and a closed position (Figures 7(b), Figure 8(b)). As previously, a non-return arrangement may be provided so that, when the cover 64 is closed over the storage compartment 62, it cannot be reopened.

Referring now to Figures 9 and 10, these illustrate two different stacking configurations for the storage and removal compartments 70, 72 when they are oppositely directed. Figure 8 shows a first stacking arrangement which provides a short and squat arrangement. Here the forward part of the needle passages 74, 76 of each compartment extend and lie alongside the socket portion of the other container with the needle passages staggered longitudinally. In the arrangement of Figure 9, the needle passages 74, 76 lie alongside each other and are parallel and inversely aligned, which means that the width of the device can be reduced, but at the expense of increased height.

CLAIMS

1. A needle tip storage and removal device comprising a storage compartment (16) for receiving in use an unused needle tip (10) of a given drive configuration comprising a cylindrical skirt, and adjacent said storage compartment to a removal compartment (18) for receiving in use a used needle tip of said given configuration, wherein the removal compartment (18) includes a removal socket (28) and snap engagement means (30) adjacent the outer periphery of the socket for cooperating with said skirt to retain a used needle tip (10) when pressed into said removal socket (28) in use.

2. A needle tip storage and removal device according to Claim 1, wherein the snap engagement means (30) comprises spaced arcuate rib portions directed radially inwardly around the periphery of the removal socket (28).

3. A needle tip storage and removal device according to Claim 1 or Claim 2, wherein the removal compartment (16) is formed of moulded plastics material, and the snap engagement means (32) are formed of a different plastics material.

4. A needle tip storage and removal device according to any of the preceding Claims, wherein the removal socket (28) is designed so that in use a used needle tip (10) may be fully retained in said socket by said snap engagement means (32), without protruding beyond the socket.

5. A needle tip storage and removal device as claimed in any of the preceding Claims, wherein the storage container includes wall regions (36) extending away from the socket (28) to define a dished profile when viewed in a

direction transverse to a direction in which a used needle tip (10) is inserted into the removal compartment (18) in use.

6. A needle tip storage and removal device according to any of the preceding Claims, including a peripheral flange (34) extending around at least part of the periphery of the removal socket (28) and having a textured surface.

7. A needle tip storage and removal device according to Claim 6, wherein the textured surface is roughened or jagged.

8. A needle tip storage and removal device according to any of the preceding Claims which includes a movable closure element (38, 54, 64) associated with the device and movable between an open position in which the removal socket (18) is accessible and a closed position in which the closure element closes the socket preventing access to the socket (18) and any needle tip (10) contained therein.

9. A needle tip storage and removal device according to Claim 8, wherein the closure element comprises a cap (38) hinged to the device and hingeable between said open and closed positions.

10. A needle tip storage and removal device according to Claim 9, wherein said cap (38) and said hinge (40) are integrally moulded with said removal compartment (18).

11. A needle tip storage and removal device according to Claim 9 or Claim 10, wherein said cap (38) includes a feature (42) that cooperates with a corresponding feature (30) adjacent the socket to provide a snap engagement when the cap is closed.

12. A needle tip storage and removal device according to Claim 8,

wherein said closure element (54, 64) is slideable between said open and closed positions.

13. A needle tip storage and removal device according to Claim 12, wherein said closure element includes a flexible member (54) slideably mounted within an outer housing of said device and having an externally accessible pad (58) for manual engagement to move said closure element between its open and closed positions.

14. A needle tip storage and removal device according to Claim 12, wherein said closure element comprises a shutter (64) mounted on the exterior of the device and movable between open and closed positions.

15. A needle tip storage and removal device according to Claim 14, wherein said shutter (64) includes spaced claw members (65) adapted to slide in corresponding tracks (66) in an outer housing.

16. A needle tip storage and removal device according to any of the preceding Claims, wherein each of the storage and removal compartments (16, 18) comprises walls defining a generally cylindrical socket (26, 28) for the hub of the needle tip, and extending away therefrom an elongate narrower passage (24) to receive the needle (14) of the needle tip (10), with the storage compartment (16) and the removal compartment (18) being oppositely directed.

17. A needle tip storage and removal device according to Claim 16, wherein the forward end of the passage (24) in a given compartment (16, 18) lies alongside the cylindrical socket (28, 26) of the other, with the passages staggered

18. A needle tip storage and removal device according to Claim 16,

wherein the passages (24) lie generally parallel and alongside each other and project towards the socket of the other compartment.

19. A needle tip storage and removal device comprising a storage compartment (16) for receiving in use an unused needle tip (10) of a given drive configuration comprising a cylindrical skirt, and adjacent the storage compartment to a removal compartment (18) for receiving in use a used needle tip of said given configuration, wherein the removal compartment (18) includes a movable closure element (38, 54, 64) associated with the device and movable between an open position in which the removal socket (18) is accessible and a closed position in which the closure element closes the socket (18) preventing access to the socket and any needle tip contained therein.

20. A needle tip storage and removal device according to Claim 19, wherein the closure element comprises a cap (38) hinged to the device and hingeable between said open and closed positions.

21. A needle tip storage and removal device according to Claim 20, wherein said cap (38) and said hinge (40) are integrally moulded with said removal compartment (18).

22. A needle tip storage and removal device according to Claim 19 or Claim 20, wherein said cap (38) includes a feature (42) that cooperates with a corresponding feature (30) adjacent the socket to provide a snap engagement when the cap is closed.

23. A needle tip storage and removal device according to Claim 19, wherein said closure element (54, 64) is slideable between said open and closed positions.

24. A needle tip storage and removal device according to Claim 23, wherein said closure element includes a flexible member (54) slideably mounted within an outer housing of said device and having an externally accessible pad (56) for manual engagement to move said closure element between its open and closed positions.

25. A needle tip storage and removal device according to Claim 23, wherein said closure element comprises a shutter (64) mounted on the exterior of the device and movable between open and closed positions.

26. A needle tip storage and removal device according to Claim 25, wherein said shutter (64) includes spaced claw members (65) adapted to slide in corresponding tracks (66) in an outer housing.

27. A needle tip storage and removal device comprising a storage compartment (16) for receiving in use an unused needle tip (16) of a given drive configuration comprising a cylindrical skirt, and adjacent the storage compartment to a removal compartment (18) for receiving in use a used needle tip of said given configuration, wherein each of the storage and removal compartments (16, 18) comprises walls defining a generally cylindrical socket (26, 28) for the hub of the needle tip (10), and extending away therefrom an elongate narrower passage (24) to receive the needle of the needle tip, with the storage compartment (16) and the removal compartment (18) being oppositely directed, and wherein the forward end of the passage (24) in a given compartment lies alongside the cylindrical socket of the other, in staggered configuration.

Application No:	GB1121667.8	**Examiner:**	Emily Jones
Claims searched:	1-18	**Date of search:**	21 March 2012

Patents Act 1977: Search Report under Section 17

Documents considered to be relevant:

Category	Relevant to claims	Identity of document and passage or figure of particular relevance
X	1-18	US 2010/063457 A1 (OWEN MUMFORD LTD) See Paragraph 0016 and note threaded collar 12 with splines 14, unused needle storage compartment 20, used needle removal compartment 26 and complementarily splined socket 22
X	1-18	WO 2010/042680 A1 (ULTIMED INC et al) See Figures 3, 5, pages 7-8, and note container 22 for unused sharps and container 24 for used sharps and aperture 12
X	1-18	US 5554129 A (STEVENSON) See column 4 line 59 - column 5 line 11 and note unused needle compartment 20, used needle compartment 26 and flanges 86
X	1-18	US 2009/236347 A1 (ERICKSON et al) See Figure 2 and note sharps container with frustoconical receiving means 20, receiving aperture 24 and interior partition 60 1-18
X	1-5 and 8-11	EP 2298224 A1 (BECTON DICKINSON CO) See paragraph 0031 and note hub 20 and needle 11, opening 137, sharps disposal container 121 and caps 251, 255
A	-	US 6923318 B1 (ERICKSON et al) Note housing 10, storage section 11, rim 11A, used syringe receiving means SRM-1 and SRM-2, receiving and holding recess 31A and inwardly extending ribs 34
A	-	US 2008/308441 A1 (ERICKSON et al) See Figure 14
A	-	US 2005/016883 A1 (PHAN) See abstract and description

Categories:

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date

earlier than, the filing date of this application.

Field of Search:

Search of GB, EP, WO & US patent documents classified in the following areas of the UKC[X] :

Worldwide search of patent documents classified in the following areas of the IPC

A61B; A61M

The following online and other databases have been used in the preparation of this search report

WPI, EPODOC

International Classification:

Subclass	Subgroup	Valid From
A61M	0005/32	01/01/2006
A61M	0005/00	01/01/2006
A61B	0019/02	01/01/2006

Application No: GB1121667.8 **Examiner:** Emily Jones

Claims searched: 19-26 **Date of search:** 9 August 2012

Patents Act 1977
Further Search Report under Section 17

Documents considered to be relevant:

Category	Relevant to claims	Identity of document and passage or figure of particular relevance
X	19-26	GB 2437923 A (OWEN MUMFORD LTD) Note needle storage compartment 20, used needle removal compartment 26 and a foil sealing element 24.
X	19-26	EP 2298224 A1 (BECTON DICKINSON CO) Note container 101, storage container 141, disposal container 121 and lid 131. The lid may further comprise plugs 251, for securing the needles inside their respective containers.
X	19-26	WO 2010/042680 A1 (ULTIMED INC et al) Note first compartment 22, first aperture 14, second compartment 24, second aperture 12 and hopper 18
X	19-26	US 2006/243619 A1 (BROWN et al) Note collection container 110, dispensing container 120, inlet 111 and lid 112.
X	19-26	US 2008/308441 A1 (ERICKSON et al) See Figure 14 and note container body 102, wall 138, first chamber 140, second chamber 142 and lids 114, 136.
X	19-26	EP 2257236 A1 (ERICKSON et al) Note interior partition 60 and ejector mechanism 28.

Categories:

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
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&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.

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A61B	0019/02	01/01/2006

Application No: GB1121667.8 **Examiner:** Emily Jones

Claims searched: 27 **Date of search:** 9 August 2012

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Further Search Report under Section 17

Documents considered to be relevant:

Category	Relevant to claims	Identity of document and passage or figure of particular relevance
X	27	US 2010/063457 A1 (OWEN MUMFORD LTD) See Figure 1, noting storage compartment 20, removal compartment 27 and socket 22.
X	27	US 5554129 A (STEVENSON) See Figures 4, 7 and 8 and note storage compartment 20 and removal compartment 26.

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